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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/109,082	07/02/98	MELKI J	2121-140P

002292 HM12/0130
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EXAMINER	
HAYES, R	
ART UNIT	**PAPER NUMBER**
1647	18

DATE MAILED: 01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/109,082	Applicant(s) Melki et al
	Examiner Robert C. Hayes	Group Art Unit 1647

☒ Responsive to communication(s) filed on *Oct 4, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-52* is/are pending in the application.

Of the above, claim(s) *1-20, 24-29, 35, and 37-39* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *21-23, 30-34, 36, and 40-52* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-52* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group IV, claims 21-23, 30-34, 36 & 40-52, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-20, 24-29, 35 & 37-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected inventions. Election was made **without** traverse in Paper No. 6, and therefore, is made FINAL.

This application contains claims 1-20, 24-29, 35 & 37-39 are drawn to an invention nonelected without traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
-it does not identify the citizenship of each inventor.

Claim Objections

3. Claims 33 & 37 are objected to because it does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification **and claims** wherever a reference is made to that sequence (i.e., as it relates to various recited exons to various recited genes). See M.P.E.P. 2422.04. Note, that references to sequences in Figures do not comply with 37 C.F.R. § 1.821(d); consistent with the notice to comply with the SEQUENCE RULES in Paper NOs. 7, 12 & 14. Failure to comply with the SEQUENCE RULES in the **claims** will be held as a non-responsive action, and may result in abandonment of this application as stated in Paper NOs. 7, 12 & 14.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-23, 30-34, 36 & 40-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting specific motor disease states related to specific mutations of specific nucleotide sequences (i.e., by SEQ ID NO) using structurally definable probes (i.e., by SEQ ID NO) and known restriction enzymes to generate detectable and definable polymorphisms, does not reasonably provide enablement for any generic

method that does not identify the specific disease state being detected, especially when using structurally uncharacterized probes that may or may not identify specific portions of undefined or unknown genes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The name, "T-BCD541 gene" or "SMN gene", alone encompasses any random mutation, addition, substitution, deletion, fragment or any biologically functional equivalent nucleic acid molecule, which provides no structural characterization and little functional characteristics for knowing how to make and use the instant invention. The specification also fails to provide sufficient guidance for defining what specific nucleotide residues are critical for distinguishing any undefined motor neuron disorder involving a SMN-/ T-BCD541-related gene from any different motor neuron disorder involving some alteration in a different nucleic acid molecule. In other words, the skilled artisan would reasonably expect that random mutations manifested in any reference SMN-related gene (which is not adequately claimed) would result in a method that already encodes an inactive SMN protein, and therefore, a method that cannot distinguish whether or not a motor neuron disorder exists; even if structurally definable probes were recited in the claims that accurately distinguish a mutated SMN gene from a normal SMN gene. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger then states on

page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for distinguishing what constitutes a normal/ wildtype SMN gene from a dysfunctional SMN gene would prevent the skilled artisan from determining whether a structurally uncharacterized/mutated reference nucleic acid molecule (i.e., as currently encompassed by the claims) could be reasonably correlated with the presence or absence of a motor neuron disorder, because any such random modification/mutation manifested within a SMN-related reference gene would be predicted to result in a method that does not work without requiring undue experimentation to determine each unique, and otherwise unknown mutations; especially for all motor neuron-related genes currently encompassed by claims 21-22, 30 & 32).

It is suggested that amending the claims to define what structurally characterizes a reference wildtype SMN/ T-BCD541 gene (i.e., by SEQ ID NO), and to then define specific probes (i.e., by SEQ ID NO), conditions and method steps that reasonably distinguishes a mutated SMN gene from the wildtype T-BCD541 gene (i.e., as it especially relates to definable portions thereof of claim 33) should obviate this rejection.

5. Claims 36 & 40-52 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The appropriate ATCC numbers and required Deposit

information critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification lacks any deposit information for the deposit of any DNA molecule containing the "T-BCD541 gene" or "SMN gene". Because these undefined genes are unknown, and therefore, publicly not available or can reproducibly isolated from nature without undue experimentation, a suitable deposit for patent purposes is required.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification. In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Amendment of the specification to recite the date of deposit, the complete name and address of the depository, along with a *chain of custody,* are required.

6. Claims 21-23 & 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are dependent on non-elected base claims.

7. Claims 23, 30-32, 36, 40, 48 & 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is ambiguous what the recitations, "SCCP", or "SMA", exactly entail. It is suggested that the claims be amended to recite what these abbreviations actually mean. In addition, it is unknown what metes and bounds define SCCP, since no such conditions are recited; thereby, also being incomplete.

8. Claims 30-33 & 36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See

MPEP § 2172.01. The omitted steps are: when "detecting the presence or absence of the motor neuron disorder/AMC" (i.e., as it relates to claim 21 & 36, respectively), or when "detecting spinal muscular atrophy" (i.e, as it relates to the preamble of claim 33), is completed.

9. Claims 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unknown what metes and bounds "stringent hybridization conditions" entail, in that it is unknown whether low, moderate or high stringent conditions are envisioned; nor what exactly defines these conditions.

10. Claims 21-23, 40, 43, 46-49 & 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unknown what metes and bounds "an amplification reaction" (e.g., as it relates to claim 21) entail, or what constitutes "*analyzing* exon 7..." (e.g., as it relates to claim 40), since no such conditions are recited; thereby, being incomplete.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
January 29, 2001